

IN THE CIRCUIT COURT FOR
MONTGOMERY COUNTY, MARYLAND

BRIDGET CARADORI, Individually and as
Personal Representative of Patricia Daley, Deceased
260 Cook Road
E. Aurora, New York 14052,

And for the Benefit of:

ROBERT L. DALEY
5299 Curriers Road
Arcade, New York 14009,

Plaintiffs,

vs.

ETHICON, ENDO SURGERY, INC., d/b/a
ETHICON WOMEN'S HEALTH AND UROLOGY
U.S. Route 22 West
Somerville, NJ 08876-0151

Registered Agent:
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

KARL STORZ ENDOSCOPY-AMERICA INC,
2151 E Grand Avenue
El Segundo, California 90245

Registered Agent:
Paracorp Incorporated
2804 Gateway Oaks Drive, #200
Sacramento, California 95833

Civil Action No. 393031 V

KARL STORZ ENDOVISION, INC.,)

91 Carpenter Hill Road)

Charlton, Massachusetts 01507)

Registered Agent:)

Paracorp Incorporated)

10 Milk Street, Suite 1055)

Boston, MA 02108)

KARL STORZ GMBH & CO., KG, ORGANIZED)
IN GERMANY)

Mittelstr. 8, 78532 Tuttlingen)

Postfach 230, 78503 Tuttlingen)

GERMANY)

Defendants.)

COMPLAINT

NOW COMES Plaintiffs, Bridget Caradori, Administrator of the Estate of Patricia Marie Daley, deceased, and Robert Daley, by their attorneys, Annie P. Kaplan, Esq. and Fay Kaplan Law, P.A., bring this action against Ethicon Endo Surgery, Inc., Ethicon Women's Health and Urology (hereinafter, "Ethicon", collectively), Karl Storz Endoscopy-America, Inc., Inc., and Karl Storz GmBh and Co. KG (hereinafter "Storz", collectively), and respectfully alleges as follows:

INTRODUCTION

1. This is a products liability action against the manufacturers of two gynecologic surgical morcellators, the Gynecare and the Storz Morcellators, for injuries and death caused by the use of their products.

2. On February 21, 2011, Patricia Marie Daley underwent a robot-assisted hysterectomy with uterine morcellation at Holy Cross Hospital in Silver Spring, Maryland. Morcellators manufactured by the defendants were used on Ms. Daley during this surgery.

JURISDICTION AND VENUE

3. Plaintiff Bridget Caradori, is the sister of Patricia Marie Daley, deceased, and lives in New York State. She is the duly appointed Administrator of the Estate of Patricia Marie Daley, deceased, a Maryland Estate. At the time of her death Ms. Daley was a resident of the State of Maryland.

4. Plaintiff Robert Daley is the father of the decedent and a resident of New York State.

5. Defendant Karl Storz Endoscopy-America, Inc., is incorporated in the state of California, and, together with the other Defendants, is responsible for the sale, marketing, promotion, and distribution of Storz instruments, including

the Storz Morcellators, throughout the United States and the State of Maryland, directly and indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of this court. It maintains its principal place of business in El Segundo, California, and is a citizen of the state of California, according to 28 U.S.C. § 1332.

6. Defendant Karl Storz Endovision, Inc., is incorporated in the state of Massachusetts, and it manufactures Storz instruments distributed throughout the United States and the State of Maryland, directly and indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of the State of Maryland and this court. It maintains its principal place of business in Charlton, Massachusetts, and is a citizen of the state of Massachusetts.

7. Defendant Karl Storz GMBH & Co. KG, is organized in Germany and maintains its principal place of business in Tuttlingen, Germany. It is the parent company of Karl Storz Endovision, Inc., and Karl Storz Endoscopy-American, Inc. Together with the other Defendants, it is responsible for the design, production, marketing, and sale of the Storz Morcellators throughout the United States and the State of Maryland, directly and indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of this court; and for all information about the

The allegations above are incorporated by reference to support this Count.

18. The Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell products, including instruments for uterine morcellation, specifically the Gynecare and Storz Morcellatorss, in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff herein, and to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

18. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as Plaintiff herein, so as to avoid harm.

19. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, the Gynecare and Storz Morcellators, both generally and in the following particular respects:

- a. Failing to provide a closed system for use with their morcellators that would have prevented dissemination of cancer;

b. failing to conduct adequate and appropriate testing of instruments such as the Gynecare and Storz Morcellators, specifically including, but not limited to, products used for uterine morcellation;

c. placing products used for uterine morcellation such as the Gynecare and Storz Morcellators on the market without first conducting adequate testing to determine possible side effects and danger to users such as Ms. Daley.

d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, such as the Gynecare and Storz Morcellators, which testing evidenced such products potential harm to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, such as the Gynecare and Storz Morcellators which indicated such products potential harm to humans;

f. failing to promptly and adequately warn of the harmful potential of the products used for uterine morcellation;

g. failing to promptly and adequately warn of the risk for the metastatic spread of cancer when using products used for uterine morcellation, such as the Gynecare and Storz Morcellatorss;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products were used for uterine morcellation in light of such products potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation, specifically the Gynecare and Storz Morcellators, are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation , such as the Gynecare and Storz Morcellators, for use on patients given their knowledge and experience of such products' potential harmful effects;

- l. failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;
- m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of said products, specifically including products used for uterine morcellation such as the Gynecare and Storz Morcellators;
- n. placing and/or permitting the placement of the products used for uterine morcellation, specifically the Gynecare and Storz Morcellators, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;
- o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation, including the Gynecare and Storz Morcellators, to be harmful to humans;
- p. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients, including the Gynecare and Storz Morcellators;

q. disregarding the safety of users and consumers of products used for uterine morcellation, including plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

u. failing to remove products used for uterine morcellation from the stream of commerce;

v. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

- w. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods;
- x. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;
- y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries;
- z. failing to use due care under the circumstances; and,
- aa. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.
- bb. failing to develop a closed morcellator system with the deployment of an intraperitoneal ballistic bag in order to prevent this known risk of disseminating an unsuspected cancer.

20. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff suffered serious injuries, and/or financial losses and harm.

21. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by

law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT II – STRICT PRODUCTS LIABILITY

Paragraphs 1 through 21 above are incorporated by reference to support this Count.

22. Because of the unreasonably dangerous and defective condition of the products used for uterine morcellation, specifically the Gynecare and Storz Morcellators, which Defendants manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiff for her injuries, which they directly and proximately caused. They proximately and directly caused her injuries by failing to properly and adequately design the products used for uterine morcellation, specifically the Gynecare and the Storz Morcellator, in order to prevent the potential spread of malignancy.

23. In addition, the Plaintiff's injuries and losses were the direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce the products used for uterine morcellation, specifically the Gynecare and Storz Morcellators, without proper and adequate warnings regarding the potential for

said products' harm to humans and as otherwise set forth supra, when said Defendants knew or should have known of the need for such warnings and/or recommendations.

24. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT III - BREACH OF EXPRESS WARRANTY

Paragraphs 1 through 24 above are incorporated by reference to support this Count.

25. In the advertising and marketing of the products used for uterine morcellation which was directed to both physicians and hospitals and consumers, Defendants warranted that said product or products, including the Gynecare and Storz Morcellators, were safe for intended use, which induced physicians and hospitals to use the same for procedures such as the surgery Plaintiff Patricia Marie Daley, deceased underwent in February 2011.

26. The aforesaid warranties were breached by Defendants in that the Gynecare and Storz Morcellator products used for uterine morcellation constituted a serious danger to the patient.

27. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff suffered serious injuries, financial losses, and other harm.

28. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT IV – BREACH OF IMPLIED WARRANTIES

Paragraphs 1 through 28 above are incorporated by reference to support this Count.

29. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Gynecare and Storz Morcellators used for uterine morcellation.

30. At all relevant times, Defendants intended that the products used for uterine morcellation, including the Gynecare and Storz Morcellator, be used in the manner that the Plaintiff's surgeon in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

31. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellation, including Gynecare and the Storz Morcellator, were safe, and withheld and concealed information about the substantial risks of serious injury associated with using the products used for uterine morcellation;

b. Defendants represented that the products used for uterine morcellation, including, Gynecare and the Storz Morcellator, were as safe and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives available on the market; and,

c. Defendants represented that the products used for uterine morcellation, including Gynecare and the Storz Morcellator, were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

32. In reliance upon Defendants' implied warranties, Plaintiff's surgeons used said Gynecare and Storz Morcellator as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendants.

33. Defendants breached their implied warranties to Plaintiff in that said Gynecare and Storz Morcellators used for uterine morcellation was not of merchantable quality, was not safe and fit for intended use, and was not adequately tested.

34. As a direct and proximate consequence of Defendants' breach of implied warranties and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiff sustained injuries and damages alleged herein including pain and suffering.

35. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT V - FRAUDULENT MISREPRESENTATION AND OMISSION

Paragraphs 1 through 35 above are incorporated by reference to support this Count.

36. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including Gynecare and the Storz Morcellators, owed a duty to provide accurate and complete information regarding said instruments.

37. Prior to Plaintiff's surgery in February 2011, Defendants fraudulently misrepresented that the use of their Gynecare and the Storz Morcellators for uterine morcellation as safe and effective.

38. Defendants had a duty to provide Plaintiff, her physicians, and other patients and doctors concerned with true and accurate information regarding the devices for uterine morcellation they manufactured, marketed, distributed and sold, including the Gynecare and the Storz Morcellator. They failed to perform that duty, omitting material information about the instrument's risks.

39. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, and the medical community to act in reliance by purchasing and using the Gynecare and the Storz Morcellators. The Plaintiff's doctor, the Plaintiff, and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using Gynecare and the Storz Morcellators, including for Plaintiff's surgery in February, 2011.

40. Defendants' representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of the Plaintiff's injuries, specifically the disseminated cancer she suffered and died from, which

was diagnosed five months later at the time of her second laparotomy in July 21, 2011.

41. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT VI SURVIVAL ACTION
(RESTATEMENT OF TORTS, SECTION 402A)

42. The paragraphs above are incorporated by reference hereto as if set forth herein.

43. Plaintiff brings this survival action on behalf of the Estate of Patricia Marie Daley under Section 7-401 of Md. Est. & Trust Code Annotated, the applicable Rules and decisional law. Plaintiff is entitled to damages under the Survival Act because of the death of the decedent due to wrongdoing of Defendants.

44. As a result of the death of the decedent, Plaintiff sustained economic losses and damages for pecuniary losses suffered by the estate, funeral expenses and loss of earnings as provided by statute. Plaintiff also claims damages for pain and suffering, inconvenience, embarrassment, humiliation; mental anguish

endured by Plaintiff's decedent prior to her death and seeks the full measure of damages under the Survival Act.

Wherefore, Plaintiffs seek damages under Maryland's Survival statute.

COUNT VII WRONGFUL DEATH
(RESTATEMENT OF TORTS SECTION 402A)

45. The allegations contained in paragraphs 1 through 44 are adopted and incorporated herein by reference as though expressly stated.

46. Plaintiff brings this wrongful death action for the benefit of the beneficiaries of Patricia Marie Daley, deceased.

47. Plaintiff as administrator and sister of Patricia Marie Daley, deceased, brings this wrongful death complaint to recover damages for the loss of society, companionship, comfort, protection, counsel, affection, economic losses, medical expenses, and benefits they would have expected to receive from the Decedent and other damages and injuries allowed to be recovered under the Maryland wrongful death statute.

48. As a direct result of the actions of the Defendants named herein, Plaintiff and Decedents beneficiaries, to wit, her father, Robert Daley, have and will sustain injuries including, but not limited to, loss of society, companionship, protection, care, advice and guidance. They have sustained loss of pecuniary

support, gifts and other contributions and the reasonable value of services

Decedent would have provided had she lived her normal expected life.

Decedent's next of kin have also been damaged in other ways and claim those losses and benefits they are entitled to under Maryland's wrongful death statute.

Wherefore, Plaintiffs seek damages under Maryland's Wrongful Death statute.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

- A. Compensatory damages in excess of the jurisdictional amount, including, but not limited to, damages for bodily injury, pain, suffering, emotional and mental distress, loss of enjoyment of life, loss of society, aggravation of a previously existing condition and other non-economic damages in an amount to be determined by a jury at trial of this action;
- B. Medical expenses, loss of earnings, loss of the ability to earn money and other economic damages in an amount to be determined by a jury at trial of this action;

- C. All punitive damages allowed by law to be determined by a jury at trial of this action;
- D. Restitution and disgorgement of profits;
- E. Reasonable attorneys' fees;
- F. The costs of these proceedings; and
- G. Such other and further relief as this Court deems just and proper.

Dated: July 15, 2014

Respectfully Submitted,

FAY KAPLAN LAW, P.A.



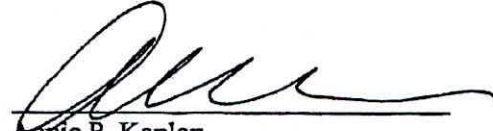
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Counsel for the Plaintiffs

JURY DEMAND

Plaintiff demands a jury to decide all triable issues.

CERTIFICATION BY SIGNING ATTORNEY

I, Annie P. Kaplan, certify on this 15th day of July 2014, as provided by Rule 1-313 of the Maryland Rules, that I have been admitted to practice law in the State of Maryland and am a member in good standing of the Maryland Bar.



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